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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,583	03/18/2004	Edgardo Costa Maiani	DID1046US	7264

9561 7590 10/06/2008  
POPOVICH, WILES & O'CONNELL, PA  
650 THIRD AVENUE SOUTH  
SUITE 600  
MINNEAPOLIS, MN 55402

EXAMINER
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CHAPMAN, GINGER T

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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10/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/804,583

**Applicant(s)**

MAIANTI ET AL.

**Examiner**

Ginger T. Chapman

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 25, 2008 has been entered.

#### ***Terminal Disclaimer***

2. The terminal disclaimer filed on September 8, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number US 2004/0223876 A1, Serial No. 10/805,165 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Status of the claims***

3. Claims 1-3 and 7 are pending in the application, claim 1 is amended.

#### ***Drawings***

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **6a**, inlet; see Specification, p. 4, l. 23. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gremel et al (US 6,302,860 B1) in view of De Wall (US 3,256,883).

8. With respect to claim 1, as best depicted in Figures 3 and 4, Gremel discloses an integrated device for oxygenating and filtering blood flowing through an extracorporeal blood circuit comprising: a bubble trap 30 having an inlet 44 for receiving venous blood and an outlet 48 for supplying venous blood; a blood pump 26 having an inlet connected to receive venous blood and an outlet; an oxygenator 28 having an inlet connected to receive venous blood and an outlet for supplying oxygenated blood; an arterial blood filter 30 having an inlet connected to receive blood and an outlet for supplying filtered blood; and a monolithic housing (fig. 4) including a first portion for defining the bubble trap (c. 2, ll. 61-63), wherein the device does not comprise a venous reservoir (c. 2, ll. 26-31; abstract).

9. Gremel discloses the claimed invention except for a heat exchanger. De Wall, at c. 1, ll. 30-33, provides motivation a heat exchanger in an integrated device for oxygenating and filtering blood. As best depicted in Figures 1 and 2, De Wall teaches a heat exchanger 52 (c. 4, ll. 28-39). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Gremel to include a heat exchanger as taught by De Wall since De Wall states, at c. 5, ll. 3-6, that the benefit of a heat exchanger is that it allows for effective temperature control of the blood.

10. With respect to claim 7, Gremel discloses the housing is configured such that blood flowing through the circuit is directed through the bubble trap before the blood enters the blood pump (fig. 3; c. 2, ll. 26-31; ll. 58-63).

11. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gremel in view of De Wall and further in view of Israeliev (US 5,924,848).

12. With regard to claims 2 and 3, Gremel in view of DeWall disclose the claimed invention except for the blood pump comprises a centrifugal pump positioned such that the axis of the pump is horizontal. Israelev teaches a centrifugal pump for extracorporeal blood circuit in which the axis of the pump may be horizontal or vertical (c. 3, ll. 58-59. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the pump of Israelev in the circuit of Gremel since Israelev states, at c. 3, ll. 54-60 that the benefit of using such a pump is that it is stable when the direction of the pump's axis of rotation is changed because the position of the housing is changed to allow for flexibility in positioning the pump.

#### ***Response to Arguments***

13. Applicant's arguments with respect to claims 1-3 and 7 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/  
Examiner, Art Unit 3761  
09/22/08

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761